

REMARKS

Status of Claims: Claim 46-51, 54-62, and 65-67 are rejected. Claims 46-51, 54-62, and 65-67 remain pending.

Obviousness Double Patenting Rejections:

The Examiner provisionally rejects all the pending claims as unpatentable over Claims 1-2 of US 6,228,055 and/or Claims 1-45 of US 2001/0034528 (US Serial number 09/776,125) and/or Claims 1-45 of US 2004/0024304 (US serial number 10/630,883).

It is respectfully urged that the provisional rejection with respect to the '055 patent is improper for all the reasons set forth in Applicants' amendment and response dated February 27, 2004. Additionally, the Examiner's most recent Office Action does not appear to address any of the arguments made by Applicant in the response of February 27, 2004. Accordingly, the Examiner is respectfully requested to consider the arguments set forth in the February 27th response and withdraw this provisional rejection.

With respect to the US 2001/0034528 publication of 09/776,125, it is respectfully urged that the rejection is improper because it is based on the published claims in the publication, and not the pending claims in 09/776,125. The Examiner is respectfully requested to consider the claims of the present application with respect to those pending in 09/776,125 (currently assigned to Examiner Jessica Baxter in Art Unit 3731). The Examiner is requested to contact the undersigned if the Examiner is unable to obtain a copy of the pending claims in the '125 application in the USPTO.

With respect to US 2004/0024304 publication of US 10/630,883, it is respectfully urged that the rejection is improper because it is based on the published claims in the publication, and not the pending claims in 10/630,883. The Examiner is respectfully requested to consider the claims of

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the present application with respect to those pending in 10/630,883 (not yet assigned per the applicant's file records). The Examiner is requested to contact the undersigned if the Examiner is unable to obtain a copy of the pending claims in the '883 application.

The Examiner may also want to consider the pending Claims of US 10/213,638 (currently assigned to Examiner Brian Szmaj in art unit 3736) and the pending claims of US 10/734,671 (not yet assigned per applicant's file records). The Examiner is requested to contact the undersigned if the Examiner is unable to obtain a copy of the pending claims in these applications in the USPTO.

102 Rejection:

Claim 46 is rejected as anticipated by Campbell '936. This rejection is improper for at least the following reasons.

Anticipation requires a single prior art reference teaches each claim limitation. Claim 46 recites, among other things, providing an introducer which includes a tube with a lumen, an axial opening, a side exit port, and a closed distal end; and ejecting a marker from a side exit port.

It is respectfully urged Campbell '936 does not teach or suggest a side exit port and a closed distal end, nor the step of ejecting a marker from a side exit port. The Examiner states that Campbell's sharp point in Figure 15 is a closed distal end. Such point is not a closed end. Further, the Examiner has ignored Campbell's own language: instead of teaching a "closed distal end", Campbell specifically teaches an "Exit end 21 of tube 20" (see column 5, lines 33-49). Such an "Exit end" does not teach or imply a "side exit port". Accordingly, Campbell does not teach or suggest either a side exit port or a closed distal end. Withdrawal of the rejection is requested.

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Obviousness Rejections:

Claims 46-51, 54-62, and 65-676 are rejected as unpatentable over Edwards '308 in view of Rank '426 and Hirsch '319. This rejection is improper for at least the following reasons.

First it is respectfully urged that the Examiner has mischaracterized Edwards '308, in that the Examiner states that Edwards '308 teach all the limitations of the current invention, but admits that Edwards does not teach marking tissue. It is respectfully urged that Edwards '308 does not teach all the limitations of the current invention. For instance, with respect to Claim 46, it is respectfully urged that Edwards does not teach providing at least one marker element in a tube, providing a shaft movably positioned in a lumen of the tube with a proximal end of the shaft extending from an axial opening in the tube, or ejecting a marker from a side exit port by applying force to the proximal end of the shaft. Accordingly, Edwards fails to teach more than just "marking tissue" as maintained by the Examiner.

The Examiner refers to element 1422 of Figure 18 of Edwards. This is a "concentric suction tube 1422" per column 12 of Edwards. It is respectfully urged that such a suction tube does not teach or suggest a shaft that is positioned in a lumen, and ejecting an object (e.g a marker) from a side exit port by applying force to a proximal end of the shaft.

Accordingly, Edwards not only fails to teach or suggest providing a marker, Edwards also does not appear to teach or suggest providing a shaft for ejecting an object from an opening. The Examiner is respectfully requested to clarify how Edwards teaches all the elements of the present invention (except marking tissue), or withdraw the rejection.

The Examiner also states that Rank '426 is in the same field of endeavor as Edwards. The Examiner is respectfully requested to explain how Rank and Edwards are in the same field, as the Examiner's own statements seem to indicate otherwise: The Examiner first states that:

"Edwards et al. '308 does not teach marking tissue at the area of interest prior to its excision."

The Examiner then goes on to say:

"In the same field of endeavor, Rank et al. '426 teach marking the tissue at the area of interest such as breast tissue..."

Accordingly, by the Examiner's own analysis Edwards is not in the field of tissue marking, and Rank is, yet the Examiner concludes the two references are in the same field of endeavor. Clarification is requested.

Further, it is respectfully urged that the Examiner has not set forth a prima facie case of obviousness. A prima facie case of obviousness requires that three basic criteria be met: 1. There must be some suggestion or motivation in the prior art to modify a reference or combine reference teachings; 2. There must be a reasonable expectation of success; and 3. The references when combined must teach or suggest all the claim limitations. (See MPEP 2143).

It is respectfully urged that the Examiner has failed to provide the motivation in the prior art for combining the references. The explanation the Examiner gives for combining Rank with Edwards is that, according to the Examiner:

"It would have been obvious to one skilled in the art at the time the invention was made to have marked the tissue of interest as taught by Rank et al. '426 in the invention of Edwards et al. '308 during biopsy in order to mark and accurately localized the area of interest prior to the excision through biopsy (see in '426 col. 1, lines 10-47). "

It is respectfully urged that this is not motivation to combine the references in such a way as to provide the present invention, but instead, is at most an argument by the Examiner that one could employ tissue marking before or after using the device of Edwards '308. This is no more than an improper "obvious to try" argument for combining two references.

Further, it is respectfully urged that even if one were motivated to mark tissue in connection with using Edwards '308 device, the Examiner has provided no motivation showing why one would be motivated to deploy the marker through the device of Edwards, as the Examiner seems to imply is obvious. In other words, if one uses the Edwards' device, why would one deploy a marker through

Edwards rather than using a device specifically for marking (eg such as Rank)? Nor has the Examiner indicated how the helical marker of Rank et al. would be deployed through the device of Edwards, if such a combination were in fact taught in the prior art.

The Examiner admits that Edwards and Rank, even if combined, do not teach a shaft for pushing a marker through "a catheter/needle". However, the Examiner maintains that in view of Hirsch, it would be obvious to replace the aspiration tube in Figure 18 of '308 with a shaft or mandrol as taught by Hirsch '319 in order to "push a marker therethrough". It is respectfully urged that this is no more than improper hindsight "picking and choosing" of various portions of three different prior art references in an attempt to reconstruct the Applicants invention. It is respectfully urged that the Examiner may not engage in such improper hindsight reliance on the Applicants specification, but instead must provide motivation in the prior art for making such a combination, including making any modifications, such as the Examiner's proposed replacement of the suction tube with a pushing element.

Even if one combined the references as suggest by the Examiner, it is respectfully urged that the rejection would be improper for at least the following reasons.

First, it is not clear that the helical marker of Rank could be advanced through the device of Edwards using a pushing element from Hirsch. Clarification is requested by the Examiner. Second, the Examiner is respectfully requested to explain how there would be any expectation of success that such a combination, if made, would be workable, without destroying the function of the device being modified. For instance, if one took out the suction tube of Edwards in Figure 18, and replaced it with a pushing element, as suggested by the Examiner, would the device of Edwards still function properly? Edwards explains that tissue or liquid can be aspirated through 1422. If one replaces tube 1422 with a pushing element in Edwards, as suggested by the Examiner, the Examiner is requested to explain how the tissue or liquid would be aspirated.

Conclusion:

The Examiner is respectfully requested to reconsider the application in view of the Remarks above and any amendments. Please call Gerry Gressel at 513 337 3535 with any questions.

Respectfully submitted,



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